January 16, 2026

Sublimed
% Rob Packard
Regulatory Consultant
Medical Device Academy
345 Lincoln Hill Road
Shrewsbury, Vermont 05738

Re: K252767
Trade/Device Name: actiTENS mini
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ, NYN, IPF, NGX, NUH
Dated: December 18, 2025
Received: December 18, 2025

Dear Rob Packard:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

AMBER T. BALLARD -S

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252767

Device Name
actiTENS mini

Indications for Use *(Describe)*
Over-the-counter use :
actiTENS Mini is intended to be used as:

Transcutaneous Electrical Nerve Stimulator (TENS), used for the following indications:
-Symptomatic relief and management of chronic, intractable pain
-Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities
-Relief of pain associated with arthritis
Programs P1, P2, P3, P4, P5, P6, P7, P8, P10, P11, P12, P13 and P15 correspond to TENS mode.

Prescription use:
actiTENS Mini is intended to be used as:

Transcutaneous Electrical Nerve Stimulator (TENS), used for the following indications:
-Symptomatic relief and management of chronic, intractable pain
-Adjunctive treatment for post-surgical and post-trauma acute pain
-Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities
-Relief of pain associated with arthritis
Programs P1, P2, P3, P4, P5, P6, P7, P8, P10, P11, P12, P13 and P15 correspond to TENS mode.

Electrical Muscle Stimulation (EMS), used for the following indications:
-Temporary relaxation of muscle spasms
-Prevent or retard disuse atrophy
-Increase of local blood flow in the treatment area
-Re-educate muscles
-Maintain or increase the range of motion
-Prevention of venous thrombosis of the calf muscles immediately after surgery
Program P9 corresponds to EMS mode.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER INFORMATION

APPLICANT
Company Name Sublimed
Address: 137 rue mayoussard
City, State, Zip Moirans 38430 France
Tel: +33668050114
Contact Name: Mr. Adrien Hallet
Contact Email: adrien.hallet@subli-med.com

CORRESPONDENT
Company Name: Medical Device Academy, Inc.
Address: 345 Lincoln Hill Road
City, State, Zip Shrewsbury, VT 05738 USA
Tel: +1.802.258.1881
Contact Name: Rob Packard
Contact Email: rob@fdaestar.com

Date Prepared: January 14, 2026

II. NAME OF THE DEVICE

Device Trade Name: actiTENS mini
Classification Name: Transcutaneous electrical nerve stimulator for pain relief Regulation: 21 CFR 882.5890
Regulatory Class: Class 2
Device Panel: Neurology
Classification Product Code: GZJ
Associated Product Codes: NYN, IPF, NGX, NUH

III. IDENTIFICATION OF THE PREDICATE

Primary Predicate
Predicate Manufacturer: Sublimed
Predicate Trade Name: actiTENS
Predicate 510(k): K202159

Secondary Predicate
Predicate Manufacturer: JKH USA, LLC
Predicate Trade Name: JKH Stimulator Plus
Predicate 510(k): K182203

No reference devices were used in this submission.

IV. DESCRIPTION OF THE DEVICE

The actiTENS mini is a connected medical device for transcutaneous electrical nerve stimulation (TENS) intended to treat pain in adults. It also contains an electrical muscle strengthening (EMS) program. It is intended for people over 22 years of age with unimpaired intellectual abilities. The actiTENS mini is fixed directly on the body using a fastening accessory. It adapts to the shape of the body with its flexible design. The actiTENS mini can be used discreetly during daily activities.

The EIG (electrical impulse generator) generates electrical impulses that are diffused in the body through skin electrodes connected to one or two channels via cables available in various lengths. Managing the EIG is done by means of the actiTENS Mobile App that allows users to control the stimulation session by choosing: a stimulation program, the number of channels used, the stimulation intensity for each channel and the stimulation duration.

It is intended to be used by the patient at home and for therapeutic application by medical professionals.

V. STATEMENT OF INTENDED USE

Over-the-counter use:
actiTENS mini is intended to be used as:
Transcutaneous Electrical Nerve Stimulator (TENS), used for the following indications:

- Symptomatic relief and management of chronic, intractable pain
- Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities
- Relief of pain associated with arthritis

Programs P1, P2, P3, P4, P5, P6, P7, P8, P10, P11, P12, P13 and P15 correspond to TENS mode.

Prescription use:
actiTENS mini is intended to be used as:
Transcutaneous Electrical Nerve Stimulator (TENS), used for the following indications:

- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities
- Relief of pain associated with arthritis

Programs P1, P2, P3, P4, P5, P6, P7, P8, P10, P11, P12, P13 and P15 correspond to TENS mode.

Electrical Muscle Stimulation (EMS), used for the following indications:

- Temporary relaxation of muscle spasms
- Prevent or retard disuse atrophy
- Increase of local blood flow in the treatment area
- Re-educate muscles
- Maintain or increase the range of motion
- Prevention of venous thrombosis of the calf muscles immediately after surgery

Program P9 corresponds to EMS mode.

INDICATIONS FOR USE COMPARISON

The subject device and primary predicate device (K202159) have the same indications for use with the exception that the predicate device does not include over-the-counter-use.

The subject device and the predicate device (K182203) have equivalent indications for use, including over-the-counter use.

VI. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

TECHNOLOGICAL COMPARISON

The subject device, primary predicate device, and secondary predicate device have equivalent technological characteristics. All three devices claim one function: electrical stimulation. Concerning the maximum output voltage and the maximum output current, the subject device and the primary predicate device have been developed as a current generator with a maximum setpoint current of 60mA and has been limited by hardware to deliver output voltage of 60V. Thus it delivers a current of 60mA at 60V for 1KΩ. Above this charge the maximum output power will decrease. In both cases the maximum output current and maximum output voltage of the subject device are in the same range to this of the predicate. The subject device presents a maximum phase charge in the same range to this of the predicate device. The maximum current density and maximum average power density are directly linked to the electrodes surfaces used with the device. They are calculated for the subject device using the smallest electrodes provided/recommended for use, the values stay in the same order of magnitude as this of the predicate device. For the maximum current density it stays under 2 mA/cm^2, and the maximum power density stays well under 0,25 W/cm^2. These technological differences between the subject and predicate device do not impact safety and effectiveness.

VII. SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

Table 1: Comparison of actiTENS mini (K252767) with actiTENS (K202159).

	actiTENS mini (K252767)	actiTENS (K202159)	Justification for differences
Indications for Use	**Over-the-counter:** **actiTENS Mini** is intended to be used as: **Transcutaneous Electrical Nerve Stimulator (TENS),** used for the following indications: - Symptomatic relief and management of chronic, intractable pain - Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities - Relief of pain associated with arthritis Programs P1, P2, P3, P4, P5, P6, P7, P8, P10, P11, P12, P13 and P15 correspond to TENS mode.	**actiTENS is intended to be used as:** • Transcutaneous Electrical Nerve Stimulator (TENS), used for the following indications: - Symptomatic relief and management of chronic, intractable pain - Adjunctive treatment for post-surgical and post-trauma acute pain - Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities - Relief of pain associated with arthritis Programs P1, P2, P3, P4, P5, P6, P7, P8, P10, P11, P12 and P13 correspond to TENS mode. -	NA: Same indications for use. OTC claims justified with secondary predicate device.

	- **Prescription use:** **actiTENS Mini** is intended to be used as: - **Transcutaneous Electrical Nerve Stimulator (TENS),** used for the following indications: Symptomatic relief and management of chronic, intractable pain - Adjunctive treatment for post-surgical and post-trauma acute pain - Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities - Relief of pain associated with arthritis Programs P1, P2, P3, P4, P5, P6, P7, P8, P10, P11, P12, P13 and P15 correspond to TENS mode.	**• Electrical Muscle Stimulation (EMS), used for the following indications:** - Temporary relaxation of muscle spasms - Prevent or retard disuse atrophy - Increase of local blood flow in the treatment area - Re-educate muscles Maintain or increase the rangeof motion - Prevention of venous thrombosis of the calf muscles immediately after surgery Program P9 corresponds to EMS mode.	

	Electrical Muscle Stimulation (EMS), used for the following indications: - Temporary relaxation of muscle spasms - Prevent or retard disuse atrophy - Increase of local blood flow in the treatment area - Re-educate muscles - Maintain or increase the range of motion - Prevention of venous thrombosis of the calf muscles immediately after surgery Program P9 corresponds to EMS mode.		

Materials	**actiTENS mini Electric Impulse Generator (EIG):** - housing: Acrylonitrile Butadiene Styrene (ABS) M203FC/ Ink: TPR P541C/ Diluent TPV - blue button: Thermolast M TM7ADT Naturel/ 3% PP5M176173-ZN mevopur dark blue - blue plastic wire-pass: Thermolast M TM6LFT Naturel + 3% PP5M176173-ZN mevopur dark blue - snap-in cable connector: Stainless Steel 316L - Velcro: Polypropylene ULTRAMATE® HTH 830 + PS30 - on-plastic labeling: THERMLfilm® ADVANTAGE™ Extreme Range with EFI Jetrion 4000/4830 Series Ink Set **Self-adhesive strips:** - Velcro: Velour 3165 Std. + adhesive PS30 - Main part: Medical grade silicon **Textile accessories**:	Not publicly disclosed	Biocompatibility assessment in accordance to ISO 10993-1

	- Main fabric: Polyamide 58%, Polyester 30%, Elastane 12% - Buckle and Velcro: Polyamide **Electrodes:** (have their own 510(k): K160138): Biocompatible hydrogel conductor, conducting part: carbon + PE; insulating base material: non-woven PET fibre, snap connector: stainless steel **Low back electrodes/multisite electrode**: (have their own 510(k): K160138):)Biocompatible hydrogel conductor, conducting part: vinyl carbon; insulating base material: non-woven PET 25 microns, Velcro: Velour 3165, snap connector: stainless steel 316. **Sensitive skin** electrodes: (have their own 510(k): K130987): Hydrogel conductor (Polyethylene Glycol, water, polyvinyl pyrrolidone, magnesium acetate) and stainless steel knit cloth.		

	UltraStim® snap **Electrodes:** have their own 510(k): K130987. for material composition please refer to their own 510((k). **Cables:** Overmolding parts: TPU, Cable conductive film: TPU, Metallic part of the snap: Nickeled brass **AC charger:** plastic housing: Polycarbonate		

Design	The actiTENS mini kit is composed of a portable generator, cables, electrodes, charger, and a transport bag: Electrodes: actiTENS mini electrodes (5 references detailed below) Cables: actiTENS mini cables used to connect actiTENS mini EIG SBM7AA100 and electrodes Power supply/ Charging system: 1 Li-Ion battery <u>The standard actiTENS mini kit includes the following elements:</u> - 1 actiTENS mini - 1 armband actiTENS 70cm - 1 pack of 2 medium cables of 14 cm - 1 pack of 2 medium cables of 40 cm - 1 pack of 2 medium cables of 70 cm - 1 pack of 4 electrodes 50mm x 50mm - To charge the device:	Not publicly disclosed	The main difference in the composition of the kit is the charging system: To charge the actiTENS device, the EIG must be in the charging case, and the charging case plugged into the AC Charger. actiTENS mini kit does not include the charging case. To charge the device, the EIG is plugged directly into the mains charger via a USB-C port with 2 MOPP. A risk analysis was carried out and risk controls were implemented to ensure that this change does not affect the safety and effectiveness of the device. Finally, actiTENS mini offers optional accessories purchased separately, giving users variety (cable length, electrodes sizes, etc) for treatment.

	o 1 AC charger - 1 IFU <u>Optional accessories:</u> - Pack of 4 round electrodes diameter 32mm - Pack of 4 round electrodes diameter 50mm - Pack of 4 rectangular electrodes 50 x 90mm - 1 pack of 4 electrodes 50mm x 50mm - Low back electrode - Multisite electrode - Sensitive skin Electrodes - UltraStim® snap Electrodes - Pack of 2 cables 100 cm long - Textile fastening accessories 1 pack of 2 self-adhesive supports to fix 1 actiTENS mini on the body		

Product classification	GZJ, NGX, NYN, IPF, NUH	GZJ, NGX, NYN, IPF	The subject device includes an additional product classification code of NUH. The risks of OTC indications are addressed by the use of a secondary predicate.
Prescription or OTC	OTC and Prescription	Prescription	actiTENS mini has a secondary predicate device that is OTC for assessing substantial equivalence
Other Features	To be used with actiTENS Mobile app	To be used with actiTENS Mobile app	Same mobile app.
Power source(s)	Battery powered (1 rechargeable Li-ion battery)	Battery powered (2 rechargeable Li-Ion batteries)	actiTENS, with two batteries, and actiTENS mini, with one battery, both provide the same maximum power output of 0.222W. Therefore, this difference does not impact the safety and effectiveness of the device.
- Method of Line current Isolation	Output is electrically disabled when connect to charger via microprocessor charging circuit	Output is electrically disabled when connect to charger via microprocessor charging circuit	Same method of line current isolation
- Patient leakage current: Normal condition (μA)	NA battery powered	Not publicly disclosed	Values of the predicate are not publicly available.
- Patient leakage current: Single Fault condition (μA)	NA battery powered	Not publicly disclosed	Values of the predicate are not publicly available.
Number of output modes	1 (Maximum 60V and 60mA)	Not publicly disclosed	Values of the predicate are not publicly available.
Waveform	Compensated asymmetrical biphasic waves	asymmetrical biphasic waves	Same waveform.
Shape	Rectangular	Not publicly disclosed	Values of the predicate are not publicly available.

Maximum Output Voltage (Volts) (+/- 20 %) at 500 Ω	P1:29,3 P2:29,3 P3:29,3 P4:29,3 P5:29,3 P6:29,3 P7:29,3 P8: 29,3 P9 min (30 Hz - 150 µs): 29,3 P9 - EMS 1: 29,3 P9 max (80 Hz - 400 µs): 29,3 P10: 29,3 P11: 29,3 P12: 29,3 P13: 29,3 P15 min (1 Hz - 50 µs): 29,3 P15 max (120 Hz - 400 µs): 29,3	P1: 30,2 P2: 30,2 P3: 30 P4: 30,2 P5: 30,2 P6: 30 P7: 30,2 P8:30, 2 NA P9: 29,5 NA P10: 29,1 P11: 29,3 P12: 30,2 P13: 30,2 NA NA	Maximum output voltage of the subject device is in the range or below this of the predicate device. These technological differences between the subject and predicate device do not impact safety and effectiveness

Maximum Output Voltage (Volts) (+/- 20 %) at 2 kΩ	P1: 58 P2: 58 P3: 58 P4: 58 P5: 58 P6: 58 P7: 58 P8: 58 P9 min (30 Hz - 150 µs): 58 P9 - EMS 1: 58 P9 max (80 Hz - 400 µs): 59 P10: 58 P11: 58 P12: 58 P13: 58 P15 min (1 Hz - 50 µs): 58 P15 max (120 Hz - 400 µs): 58	P1: 57,9 P2: 57,9 P3: 57,9 P4: 57,9 P5: 57,9 P6: 57,9 P7: 57,9 P8:57,9 NA P9:57,9 NA P10: 57,9 P11: 57,9 P12: 57,9 P13:57,9 NA NA	Maximum output voltage of the subject device is very near to this of the predicate device. These technological differences between the subject and predicate device do not impact safety and effectiveness

Maximum Output Voltage (Volts) (+/- 20 %) at 10 kΩ	NA: The EIG monitors the impedance of each channel and stops any running program (or refuses to launch one) if the measured impedance is out of a specified range. This feature ensures a proper installation of the EIG, the cables and electrodes. If an electrode peels off, stopping the stimulation program quickly enough prevents the patient from feeling an electric discharge as the attached surface diminishes. The 10 kOhm is at the upper range and the EIG refused to launch a stimulation program, thus the measurement could not be performed	NA: The EIG monitors the impedance of each channel and stops any running program (or refuses to launch one) if the measured impedance is out of a specified range. This feature ensures a proper installation of the EIG, the cables and electrodes. If an electrode peels off, stopping the stimulation program quickly enough prevents the patient feeling an electric discharge as the attached surface diminishes. The 10kΩ is at the upper range and the EIG refused to launch a stimulation program, thus the measurement could not be performed.	NA: no differences

Maximum Output Current (mA) (+/-20%) at 500 Ω *calculated:* *I (A) = U (V) / R (Ω)* *with* *U = value #1 (V)* *and R = 500 Ω* *This result is multiplied by 10^3 to obtain I in mA*	P1:58,6 P2: 58,6 P3: 58,6 P4: 58,6 P5: 58,6 P6: 58,6 P7: 58,6 P8: 58,6 P9 min (30 Hz - 150 µs): 58,6 P9 - EMS 1: 58,6 P9 max (80 Hz - 400 µs): 58,6 P10: 58,6 P11: 58,6 P12: 58,6 P13: 58,6 P15 min (1 Hz - 50 µs): 58,6 P15 max (120 Hz - 400 µs): 58,6	P1:60,4 P2:60,4 P3:60 P4:60,4 P5:60,4 P6:60 P7:60,4 P8:60,4 NA P9:59 NA P10:58,2 P11:58,6 P12:60,4 P13:60,4 NA NA	Maximum output current of the subject device is in the range or below this of the predicate device. They are under the maximum average current of 10 mA into a load of 500 ohms defined in the ANSI AAMI NS4 § 3.2.2.2. These technological differences between the subject and predicate device do not impact safety and effectiveness

Maximum Output Current (mA) (+/-20%) at 2 kΩ	P1: 29 P2: 29 P3: 29 P4: 29 P5: 29 P6: 29 P7: 29 P8: 29 P9 min (30 Hz - 150 µs): 29 P9 - EMS 1: 29 P9 max (80 Hz - 400 µs): 29,5 P10: 29 P11: 29 P12: 29 P13: 29 P15 min (1 Hz - 50 µs): 29 P15 max (120 Hz - 400 µs): 29	P1: 28,95 P2: 28,95 P3: 28,95 P4: 28,95 P5: 28,95 P6: 28,95 P7: 28,95 P8:28,95 NA P9:28,95 NA P10: 28,95 P11: 28,95 P12: 28,95 P13:28,95 NA NA	Maximum output current of the subject device is very near to this of the predicate device. These technological differences between the subject and predicate device do not impact safety and effectiveness

Maximum Output Current (mA) (+/-20%) at 10 kΩ	NA: The EIG monitors the impedance of each channel and stops any running program (or refuses to launch one) if the measured impedance is out of a specified range. This feature ensures a proper installation of the EIG, the cables and electrodes. If an electrode peels off, stopping the stimulation program quickly enough prevents the patient from feeling an electric discharge as the attached surface diminishes. The 10 kOhm is at the upper range and the EIG refused to launch a stimulation program, thus the measurement could not be performed	NA: The EIG monitors the impedance of each channel and stops any running program (or refuses to launch one) if the measured impedance is out of a specified range. This feature ensures a proper installation of the EIG, the cables and electrodes. If an electrode peels off, stopping the stimulation program quickly enough prevents the patient feeling an electric discharge as the attached surface diminishes. The 10kΩ is at the upper range and the EIG refused to launch a stimulation program, thus the measurement could not be performed	NA: no differences

Pulse Width (µs)	P1: 198 P2: 148 P3: 248 P4: 198 P5: 148 P6: 198 or 148 P7: 148 P8: modulated 98 -198 P9 min (30 Hz - 150 µs): 147,5 P9 - EMS 1: 248 P9 max (80 Hz - 400 µs): 397 P10: 148 P11: 148 P12: 58 P13: 178 P15 min (1 Hz - 50 µs): 47 P15 max (120 Hz - 400 µs): 398	P1: 197,5 P2: 147 P3: 247,5 P4: 197,5 P5: 147,5 P6: 200 or 147 P7: 147,5 P8: modulated 100- 200 NA P9:247,5 NA P10: 147,5 P11: 147,5 P12: 57,5 P13:177,5 NA NA	Pulse width of the subject device is very near to this of the predicate device for the corresponding programs. Extra programs have lower (47 µs vs 100 µs) and higher (up to 398 µs vs 247,5 µs) pulse width, staying in the same order of magnitude. These technological differences between the subject and predicate device do not impact safety and effectiveness

Frequency (Hz)	P1: 100,06 P2: 80,022 P3: 2,0006 P4: 100,06 P5: 100,03 P6: 2 or 100 P7: 100 P8: modulated 2 - 80 P9 min (30 Hz - 150 µs): 30 P9 - EMS 1: 50,02 P9 max (80 Hz - 400 µs): 80 P10: 80,02 P11: 80,02 P12: 80,06 P13: 10,006 P15 min (1 Hz - 50 µs): 1,0003 P15 max (120 Hz - 400 µs): 120,08	P1: 100 P2: 80 P3: 2 P4: 100 P5: 100 P6: 2 or 100 P7: 100 P8: modulated 2- 80 NA P9:50 NA P10: 80 P11: 80 P12: 80 P13: 10 NA NA	Frequency of the subject device is very near to this of the predicate device for the corresponding programs. Extra programs have lower (1 Hz vs 2 Hz) and higher (up to 120 Hz vs 100 Hz) frequency, staying in the same order of magnitude. These technological differences between the subject and predicate device do not impact safety and effectiveness
For interferential modes only: - Beat Frequency (Hz)	NA : not interferential mode	Not publicly disclosed	Values of the predicate are not publicly available.
For multiphasic waveforms only: - Symmetrical phases? Yes / No - Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	Biphasic - No, asymmetrical Phase 1 : corresponds to the pulse width Phase 2 (discharge duration) : 120 µs +/- 10 µs	Biphasic - No, asymmetrical not publicly disclosed	Same. Values of the predicate are not publicly available.

Net Charge (µC per pulse) at 500Ω	0	Not publicly disclosed	Values of the predicate are not publicly available. Zero net charge is obtained through compensated asymmetrical biphasic waves.
Maximum Phase Charge (µC) at 500 Ω *calculated:* *Q (C) = I (A) x d (s)* *with* *I and d values measured above. This result is multiplied by 10^6 to obtain Q in µC*	P1: 11,6 P2: 8,7 P3: 14,5 P4: 11,6 P5: 8,7 P6: 8,7 to 11,6 P7: 8,7 P8: 5,7 to 11,6 P9 min (30 Hz - 150 µs): 8,6 P9 - EMS 1: 14,5 P9 max (80 Hz - 400 µs): 23,3 P10: 8,7 P11: 8,7 P12: 3,4 P13: 10,4 P15 min (1 Hz - 50 µs): 2,8 P15 max (120 Hz - 400 µs): 23,3	P1: 11,9 P2: 8,9 P3: 14,9 P4: 11,9 P5: 8,9 P6: 12,1 P7: 8,9 P8: 6,0 to 12,1 NA P9:14,6 NA P10: 8,6 P11: 8,6 P12: 3,5 P13:10,7 NA NA	Maximum phase charge of the subject device is very near to this of the predicate device for the corresponding programs. Extra programs have lower (2,8 µC vs 3,5 µC) and higher (up to 23,3 µC vs 14,9 µC) maximum phase charge, staying in the same order of magnitude. They are under the maximum charge per pulse of 31,2 µC defined in the ANSI AAMI NS4 § 3.2.2.2. These technological differences between the subject and predicate device do not impact safety and effectiveness

conductive surface area of the smallest electrodes provided/recommended for use with the unit (cm^2) *calculated:* *- for actiTENS mini: round electrodes of diameter 32 mm S (cm^2) = π x (3,2 / 2)²* *- for actiTENS: square electrodes of side length 4,5 cm S (cm^2) = 4,5 x 4,5*	8.0	Not publicly disclosed	Values of the predicate are not publicly available.

Maximum Current Density (mA/cm²) at 500 Ω *calculated along Guidance "Guidance Document for Powered Muscle Stimulator 510(k)s", issued on June 1999, p13-14.* *Maximum current density (mA/cm²) = I (mA) x f (Hz) x d (s) / S (cm²)* *With I, f, d and S values measured above*	P1: 0,144 P2: 0,086 P3: 0,004 P4: 0,144 P5: 0,108 P6: 0,003 or 0,108 P7: 0,108 P8: 0,003 or 0,057 P9 min (30 Hz - 150 µs): 0,032 P9 - EMS 1: 0,090 P9 max (80 Hz - 400 µs): 0,231 P10: 0,086 P11: 0,086 P12: 0,034 P13: 0,013 P15 min (1 Hz - 50 µs): 0,000 P15 max (120 Hz - 400 µs): 0,348	P1: 0,059 P2: 0,035 P3: 0,001 P4: 0,059 P5: 0,044 P6: 0,001 or 0,044 P7: 0,044 P8: 0,001 to 0,024 NA P9:0,036 NA P10: 0,034 P11: 0,034 P12: 0,014 P13:0,005 NA NA	Maximum current density of the subject device stays in the same order of magnitude as this of the predicate device (from 0,0003 mA/cm² vs 0,001 mA/cm² up to 0,348 mA/cm² vs 0,059 mA/cm²). These values stay under 2 mA/cm². These technological differences between the subject and predicate device do not impact safety and effectiveness.

Maximum Power Density (mW/cm^2) at 500 Ω *calculated along Guidance "Guidance Document for Powered Muscle Stimulator 510(k)s", issued on June 1999, p13-14.* *Maximum power density (mW/cm^2) = U (V) x Maximum current density (mA/cm^2) with U and Maximum current density measured above*	P1: 4,23 P2: 2,53 P3: 0,11 P4: 4,23 P5: 3,16 P6: 0,08 or 3,160 P7: 3,16 P8: 0,08 to 1,67 P9 min (30 Hz - 150 µs): 0,94 P9 - EMS 1: 2,65 P9 max (80 Hz - 400 µs): 6,78 P10: 2,53 P11: 2,53 P12: 0,99 P13: 0,38 P15 min (1 Hz - 50 µs): 0,01 P15 max (120 Hz - 400 µs): 10,20	P1: 1,78 P2: 1,06 P3: 0,04 P4: 1,78 P5: 1,33 P6: 0,04 or 1,31 P7: 1,33 P8: 0,04 to 0,72 NA P9:1,06 NA P10: 0,99 P11: 1,00 P12: 0,41 P13:0,16 NA NA	Maximum power density of the subject device stays in the same order of magnitude as this of the predicate device (from 0,01 mW/cm^2 vs 0,04 mW/cm^2 up to 10,20 mW/cm^2 vs 1,78 mW/cm^2). These values stay well under 0,25 W/cm^2 as required by the guidance "Guidance Document for Powered Muscle Stimulator 510(k)s", issued on June 1999, p 14, to reduce the risk of thermal burns. These technological differences between the subject and predicate device do not impact safety and effectiveness.
Burst Mode (i.e., pulse trains) a. Pulses per burst b. Bursts per second c. Burst duration (seconds) d. Duty Cycle [Line (b) x Line (c)]	All programs except P7: NA (continuous) Burst mode for TENS functionality: P7 a: 25 b: 2 c: 0.25 d: 0.5	Not publicly disclosed	Values of the predicate are not publicly available.

ON Time (seconds)	P1: NA (continuous) P2: NA (continuous) P3: NA (continuous) P4: NA (continuous) P5: NA (continuous) P6: NA (continuous) P7: NA (burst) P8: NA (continuous) P9 min (30 Hz - 150 µs): 1 P9 - EMS 1: 5 P9 max (80 Hz - 400 µs): 60 P10: NA (continuous) P11: NA (continuous) P12: NA (continuous) P13: NA (continuous) P15 min (1 Hz - 50 µs): NA (continuous) P15 max (120 Hz - 400 µs): NA (continuous)	Not publicly disclosed	Values of the predicate are not publicly available.

OFF Time (seconds)	P1: NA (continuous) P2: NA (continuous) P3: NA (continuous) P4: NA (continuous) P5: NA (continuous) P6: NA (continuous) P7: NA (burst) P8: NA (continuous) P9 min (30 Hz - 150 µs): 60 P9 - EMS 1: 12 P9 max (80 Hz - 400 µs): 1 P10: NA (continuous) P11: NA (continuous) P12: NA (continuous) P13: NA (continuous) P15 min (1 Hz - 50 µs): NA (continuous) P15 max (120 Hz - 400 µs): NA (continuous)	Not publicly disclosed	Values of the predicate are not publicly available.
Additional features	NA	Not publicly disclosed	no additional features
Number of output channels - *Synchronous or Alternating?* - *Method of Channel Isolation:*	2 - Alternating - Mechanical	Not publicly disclosed	Values of the predicate are not publicly available.
Regulated Current or Regulated Voltage?	Regulated current	Not publicly disclosed	Values of the predicate are not publicly available.
Software/Firmware/Microprocessor Control?	Yes, software control	Not publicly disclosed	Values of the predicate are not publicly available.
Automatic Overload Trip?	No, overload not possible by design	Not publicly disclosed	Values of the predicate are not publicly available.

Automatic No-Load Trip?	Yes, verification step during program launch and stimulation stops in case of detection of no-load.	Not publicly disclosed	Values of the predicate are not publicly available.
Automatic Shut Off?	Yes, the generator turns off after 10 minutes of no activity.	Not publicly disclosed	Values of the predicate are not publicly available.
Patient Override Control?	Yes, through the mobile app	Not publicly disclosed	Values of the predicate are not publicly available.
Timer Range (minutes)	Session duration:10 -720, adjustable via the mobile app	Not publicly disclosed	Values of the predicate are not publicly available.
Compliance with Voluntary Standards?	Yes (specified at the end of this document*)	Yes	NA: actiTENS mini complies with the standards to which actiTENS complies
Compliance with 21 CFR 898?	Yes	Yes	NA: No difference
Weight	~ 60 g	Not publicly disclosed	Values of the predicate are not publicly available.This doesn't have an impact on safety and effectiveness of the device.
Dimensions (mm) [W x H x D]	92 mm x 15 mm x 56 mm	Not publicly disclosed	Values of the predicate are not publicly available.This doesn't have an impact on safety and effectiveness of the device.
Indicator Display: - ON/OFF status? - Low battery? - Current level?	Yes:LED indicator / mobile app Yes:Indicated on the mobile app Yes:Indicated on the mobile app	Yes:LED indicator / mobile app Yes:Indicated on the mobile app Yes:Indicated on the mobile app	Values of the predicate are not publicly available.

Performance Testing	The following benchtop performance testing was performed: **Transportation Testing:** - Transportation test report **Self-adhesive strips wearability:** - Wearability test report of the self-adhesive strips **Interoperability:** - Validation report of the system **Usability Testing:** - Validation plan - Usability Engineering File - Usability Engineering File – final validation report	The following benchtop performance testing was performed: **Transportation Testing:** - Transportation test report **Self-adhesive strips wearability:** - Wearability test report of the self-adhesive strips **Interoperability:** - Validation report of the system **Usability Testing:** - Validation plan - Usability Engineering File - Usability Engineering File – final validation report	NA: Same testing.

Table 2: Comparison of actiTENS mini (K252767) with JKH Stimulator Plus (K182203).

	actiTENS mini (K252767)	JKH Stimulator Plus (K182203)	Justification for differences

Indications for Use	**Over-the-counter use :** **actiTENS Mini** is intended to be used as: **Transcutaneous Electrical Nerve Stimulator (TENS),** used for the following indications: - Symptomatic relief and management of chronic, intractable pain - Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities - Relief of pain associated with arthritis Programs P1, P2, P3, P4, P5, P6, P7, P8, P10, P11, P12, P13 and P15 correspond to TENS mode. Prescription use: **actiTENS Mini** is intended to be used as: **Transcutaneous Electrical Nerve Stimulator (TENS),** used for the following indications:	Over-the-Counter Use: TENS (Modes 1, 2, 4, 6, 8): PL-029K12 and PL-029K13 are used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household work activities. PL-0219K12 and PL-029K13 are also intended for symptomatic relief an management of chronic, intractable pain and relief of pain associated with arthritis. The device of PL-029K12 may be used during sleep. The device of PL-029K12 is labeled for use only with its own compatible electrodes. PMS (also called EMS, Modes 1, 3, 7): PL-029K12 and PL-029K13 are also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities. Heating: The device of PL-029K13 is intended for temporary relief of minor aches and pains.	Same indications for use as Model PL-029K12 (i.e., no heating function).

	- - Symptomatic relief and management of chronic, intractable pain - Adjunctive treatment for post-surgical and post-trauma acute pain - Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities - Relief of pain associated with arthritis Programs P1, P2, P3, P4, P5, P6, P7, P8, P10, P11, P12, P13 and P15 correspond to TENS mode. **Electrical Muscle Stimulation (EMS),** used for the following indications: - Temporary relaxation of muscle spasms - Prevent or retard disuse atrophy - Increase of local blood flow in the treatment area - Re-educate muscles - Maintain or increase the range of motion - Prevention of venous thrombosis of the calf muscles immediately	Prescription Use: PL-029K12 and PL-029K13 are intended for the following use: -Symptomatic relief and management of chronic, interactable pain -Adjunctive treatment for post-surgical and post-trauma acute pain -Relief of pain associated with arthritis -Temporary relaxation of muscle spasm -Prevention or retardation of disuse atrophy -Muscle re-education -Maintaining or increasing range of motion -Increase of local blood flow in the treatment area -Prevention of post-surgical venous thrombosis through immediate stimulation of calf muscles	

	after surgery Program P9 corresponds to EMS mode.		

Materials	**actiTENS mini Electric Impulse Generator (EIG):** - housing: Acrylonitrile Butadiene Styrene (ABS) M203FC/ Ink: TPR P541C/ Diluent TPV - blue button: Thermolast M TM7ADT Naturel/ 3% PP5M176173-ZN mevopur dark blue - blue plastic wire-pass: Thermolast M TM6LFT Naturel + 3% PP5M176173-ZN mevopur dark blue - snap-in cable connector: Stainless Steel 316L - Velcro: Polypropylene ULTRAMATE® HTH 830 + PS30 - on-plastic labeling: THERMLfilm® ADVANTAGE™ Extreme Range with EFI Jetrion 4000/4830 Series Ink Set **Self-adhesive strips:** - Velcro: Velour 3165 Std. + adhesive PS30 - Main part: Medical grade silicon **Textile accessories**:	Not publicly disclosed	Biocompatibility assessment in accordance to ISO 10993-1

	- Main fabric: Polyamide 58%, Polyester 30%, Elastane 12% - Buckle and Velcro: Polyamide **Electrodes:** (have their own 510(k): K160138): Biocompatible hydrogel conductor, conducting part: carbon + PE; insulating base material: non-woven PET fiber, snap connector: stainless steel **Low back electrodes/multisite electrode**: (have their own 510(k): K160138):)Biocompatible hydrogel conductor, conducting part: vinyl carbon; insulating base material: non-woven PET 25 microns, Velcro: Velour 3165, snap connector: stainless steel 316. **Sensitive skin** electrodes: (have their own 510(k): K130987): Hydrogel conductor (Polyethylene Glycol, water, polyvinyl pyrrolidone, magnesium acetate) and stainless steel knit cloth. **UltraStim® snap Electrodes:** have their own		

	510(k): K130987. for material composition please refer to their own 510((k). **Cables:** Overmolding parts: TPU, Cable conductive film: TPU, Metallic part of the snap: Nickeled brass **AC charger:** plastic housing: Polycarbonate		

Design	The actiTENS mini kit is composed of a portable generator, cables, electrodes, charger, and a transport bag: Electrodes: actiTENS mini electrodes (5 references detailed below) Cables: actiTENS mini cables used to connect actiTENS mini EIG SBM7AA100 and electrodes Power supply/ Charging system: 1 Li-Ion battery <u>The standard actiTENS mini kit includes the following elements:</u> - 1 actiTENS mini - 1 armband actiTENS 70cm - 1 pack of 2 medium cables of 14 cm - 1 pack of 2 medium cables of 40 cm - 1 pack of 2 medium cables of 70 cm - 1 pack of 4 electrodes 50mm x 50mm - To charge the device:	Electrical stimulation and heat	The subject device does not include the IRT product classification, and this eliminates the risks associated with that function.

	o 1 AC charger - 1 IFU <u>Optional accessories:</u> - Pack of 4 round electrodes diameter 32mm - Pack of 4 round electrodes diameter 50mm - Pack of 4 rectangular electrodes 50 x 90mm - 1 pack of 4 electrodes 50mm x 50mm - Low back electrode - Multisite electrode - Sensitive skin Electrodes - UltraStim® snap Electrodes - Pack of 2 cables 100 cm long - Textile fastening accessories 1 pack of 2 self-adhesive supports to fix 1 actiTENS mini on the body		

Product Classifications	GZJ, NGX, NYN, IPF, NUH	NUH, NGX, NYN, IRT, GZJ, IPF	The subject device does not include the IRT product classification, and this eliminates the risks associated with the heating function/indication.
Prescription or OTC	OTC and Prescription	OTC and Prescription	NA: Same
Energy Source	1 rechargeable Li-Ion battery	Rechargeable or non-rechargeable battery	actiTENS mini, with one rechargeable Li-Ion battery, provides a maximum power output of 0.222W; while the secondary predicate permits use of a rechargeable or non-rechargeable battery. The differences in the energy source from the secondary predicate do not impact the safety and effectiveness of the subject device.
Power source(s)	Battery powered (1 rechargeable Li-ion battery)	Rechargeable or non-rechargeable battery	NA : both are battery powered
- Method of Line current Isolation	Output is electrically disabled when connect to charger by means of microprocessor charging circuit	Battery Supply	Same method of line current isolation
- Patient leakage current: Normal condition (μA)	NA : battery powered	NA	Same
- Patient leakage current: Single Fault condition (μA)	NA : battery powered	NA	Same
Number of output modes	1 (Maximum 60V and 60mA)	8 (Maximum 134V and 152mA)	Maximum output voltage of the subject device is in the range or below this of the secondary predicate device. These technological differences between the subject device and the predicate do not impact safety and effectiveness.
Waveform	Compensated asymmetrical biphasic	Not publicly disclosed	Values of the predicate are not publicly available,
Shape	Rectangular	Not publicly disclosed	Values of the predicate are not publicly available.

Maximum Output Voltage (Volts) (+/- 20 %) at 500 Ω	P1:29, 3 P2:29, 3 P3:29,3 P4:29,3 P5:29,3 P6:29,3 P7:29,3 P8: 29,3 P9 min (30 Hz - 150 µs): 29,3 P9 - EMS 1: 29,3 P9 max (80 Hz - 400 µs): 29,3 P10: 29,3 P11: 29,3 P12: 29,3 P13: 29,3 P15 min (1 Hz - 50 µs): 29,3 P15 max (120 Hz - 400 µs): 29,3	Mode 1: This mode cycles the following modes Mode 2: 36,4 Mode 2: 47.6 Mode 3: 57.6 Mode 4: 29.6 Mode 6: 29.6 Mode 7:40.8 Mode 8: 24	Maximum output voltage of the subject device is in the range or below this of the predicate device. These technological differences between the subject and predicate device do not impact safety and effectiveness

Maximum Output Voltage (Volts) (+/- 20 %) at 2 kΩ	P1: 58 P2: 58 P3: 58 P4: 58 P5: 58 P6: 58 P7: 58 P8: 58 P9 min (30 Hz - 150 µs): 58 P9 - EMS 1: 58 P9 max (80 Hz - 400 µs): 59 P10: 58 P11: 58 P12: 58 P13: 58 P15 min (1 Hz - 50 µs): 58 P15 max (120 Hz - 400 µs): 58	Mode 1: This mode cycles the following modes Mode 2: 80,8 Mode 3: 96 Mode 4: 93,6 Mode 5: 66,4 Mode 6: 66,4 Mode 7:86,4 Mode 8: 53,6	Maximum output voltage of the subject device is very near to this of the predicate device. These technological differences between the subject and predicate device do not impact safety and effectiveness

Maximum Output Voltage (Volts) (+/- 20 %) at 10 kΩ	NA: The EIG monitors the impedance of each channel and stops any running program (or refuses to launch one) if the measured impedance is out of a specified range. This feature ensures a proper installation of the EIG, the cables and electrodes. If an electrode peels off, stopping the stimulation program quickly enough prevents the patient from feeling an electric discharge as the attached surface diminishes. The 10 kOhm is at the upper range and the EIG refused to launch a stimulation program, thus the measurement could not be performed	Mode 1: This mode cycles the following modes Mode 2: 134 Mode 3: 132 Mode 4: 108 Mode 5: 126 Mode 6: 126 Mode 7:129 Mode 8: 105	NA

Maximum Output Current (mA) (+/-20%) at 500 Ω *calculated:* *I (A) = U (V) / R (Ω)* *with* *U = value #1 (V)* *and R = 500 Ω* *This result is multiplied by 10^3 to obtain I in mA*	P1:58,6 P2: 58,6 P3: 58,6 P4: 58,6 P5: 58,6 P6: 58,6 P7: 58,6 P8: 58,6 P9 min (30 Hz - 150 µs): 58,6 P9 - EMS 1: 58,6 P9 max (80 Hz - 400 µs): 58,6 P10: 58,6 P11: 58,6 P12: 58,6 P13: 58,6 P15 min (1 Hz - 50 µs): 58,6 P15 max (120 Hz - 400 µs): 58,6	Mode 1: This mode cycles the following modes Mode 2: 72,8 Mode 3: 95,2 Mode 4: 115,2 Mode 5: 59,2 Mode 6: 59,2 Mode 7:81,6 Mode 8: 48	Maximum output current of the subject device is in the range or below this of the predicate device. They are under the maximum average current of 10 mA into a load of 500 ohms defined in the ANSI AAMI NS4 § 3.2.2.2. These technological differences between the subject and predicate device do not impact safety and effectiveness

Maximum Output Current (mA) (+/-20%) at 2 kΩ	P1: 29 P2: 29 P3: 29 P4: 29 P5: 29 P6: 29 P7: 29 P8: 29 P9 min (30 Hz - 150 µs): 29 P9 - EMS 1: 29 P9 max (80 Hz - 400 µs): 29,5 P10: 29 P11: 29 P12: 29 P13: 29 P15 min (1 Hz - 50 µs): 29 P15 max (120 Hz - 400 µs): 29	Mode 1: This mode cycles the following modes Mode 2: 40,4 Mode 3: 48 Mode 4: 46,8 Mode 5: 33,2 Mode 6: 33,2 Mode 7:43,2 Mode 8: 26,8	Maximum output current of the subject device is very near to this of the predicate device. These technological differences between the subject and predicate device do not impact safety and effectiveness

Maximum Output Current (mA) (+/-20%) at 10 kΩ	NA: The EIG monitors the impedance of each channel and stops any running program (or refuses to launch one) if the measured impedance is out of a specified range. This feature ensures a proper installation of the EIG, the cables and electrodes. If an electrode peels off, stopping the stimulation program quickly enough prevents the patient from feeling an electric discharge as the attached surface diminishes. The 10 kOhm is at the upper range and the EIG refused to launch a stimulation program, thus the measurement could not be performed	Mode 1: This mode cycles the following modes Mode 2: 13,4 Mode 3: 13,2 Mode 4: 10,8 Mode 5: 12,6 Mode 6: 12,6 Mode 7:12,9 Mode 8: 10,5	NA

Pulse Width (µs)	P1: 198 P2: 148 P3: 248 P4: 198 P5: 148 P6: 198 or 148 P7: 148 P8: modulated 98 -198 P9 min (30 Hz - 150 µs): 147.5 P9 - EMS 1: 248 P9 max (80 Hz - 400 µs): 397 P10: 148 P11: 148 P12: 58 P13: 178 P15 min (1 Hz - 50 µs): 47 P15 max (120 Hz - 400 µs): 398	Undisclosed for each mode. Only a value for an undetermined mode. PL-029K12: 100	These technological differences between the subject and predicate device do not impact safety and effectiveness.

Frequency (Hz)	P1: 100,06 P2: 80,022 P3: 2,0006 P4: 100,06 P5: 100,03 P6: 2 or 100 P7: 100 P8: modulated 2 - 80 P9 min (30 Hz - 150 µs): 30 P9 - EMS 1: 50,02 P9 max (80 Hz - 400 µs): 80 P10: 80,02 P11: 80,02 P12: 80,06 P13: 10,006 P15 min (1 Hz - 50 µs): 1,0003 P15 max (120 Hz - 400 µs):120.08	Mode 1: This mode cycles the following modes Mode 2: 62,5 Mode 3: 12,8~54,3 Mode 4: 1,19 Mode 5: 104,1 Mode 6: 104,1 Mode 7:19,8 Mode 8: 156,2	The difference of frequencies between the subject device and predicate device does not raise new types of safety or effectiveness questions because the user chooses the frequency through different kinds of programs using the mobile application and programs are using standard TENS stimulation frequencies.
For interferential modes only: - Beat Frequency (Hz)	NA: Not interferential mode	NA: Not interferential mode	NA
For multiphasic waveforms only: - Symmetrical phases? Yes / No - Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	Biphasic - No, asymmetrical Phase 1 : corresponds to the pulse width Phase 2 (discharge duration) : 120 µs +/- 10 µs	Not publicly disclosed	Values of the predicate are not publicly available.

Net Charge (µC per pulse) at 500 Ω	0	Not publicly disclosed	For subject device, zero net charge is obtained through compensated asymmetrical biphasic waves. Predicate net charge is not publicly available but is most certainly 0 thanks to the biphasic waves. Zero net charge is safe for the patient.
Maximum Phase Charge (µC) at 500 Ω *calculated:* *Q (C) = I (A) x d (s)* *with* *I and d values measured above. This result is multiplied by 10^6 to obtain Q in µC*	P1: 11,6 P2: 8,7 P3: 14,5 P4: 11,6 P5: 8,7 P6: 8,7 to 11,6 P7: 8,7 P8: 5,7 to 11,6 P9 min (30 Hz - 150 µs): 8,6 P9 - EMS 1: 14,5 P9 max (80 Hz - 400 µs): 23,3 P10: 8,7 P11: 8,7 P12: 3,4 P13: 10,4 P15 min (1 Hz - 50 µs): 2,8 P15 max (120 Hz - 400 µs): 23,3	Mode 1: This mode cycles the following modes Mode 2: 14,6 Mode 3: 19 Mode 4: 23 Mode 5: 11,8 Mode 6: 11,8 Mode 7:16,3 Mode 8: 9,6	Maximum phase charge of the subject device is very near to this of the predicate device. These technological differences between the subject and predicate device do not impact safety and effectiveness

Maximum Current Density (mA/cm²) at 500 Ω *calculated along Guidance "Guidance Document for Powered Muscle Stimulator 510(k)s", issued on June 1999, p13-14.* *Maximum current density (mA/cm²) = I (mA) x f (Hz) x d (s) / S (cm²)* *With I, f, d and S values measured above*	P1: 0,144 P2: 0,086 P3: 0,004 P4: 0,144 P5: 0,108 P6: 0,003 or 0,108 P7: 0,108 P8: 0,003 or 0,057 P9 min (30 Hz - 150 µs): 0,032 P9 - EMS 1: 0,090 P9 max (80 Hz - 400 µs): 0,231 P10: 0,086 P11: 0,086 P12: 0,034 P13: 0,013 P15 min (1 Hz - 50 µs): 0,0003 P15 max (120 Hz - 400 µs): 0,348	Mode 1: This mode cycles the following modes Mode 2: 0,013 Mode 3:0,003~0,014 Mode 4: 0,0003 Mode 5: 0,017 Mode 6: 0,017 Mode 7:0,004 Mode 8: 0,021	Maximum current density of the subject device stays in the same order of magnitude as this of the predicate device (from 0,0003 mA/cm² vs 0,0003 mA/cm² up to 0,348 mA/cm² vs 0,017 mA/cm²). These values stay under 2 mA/cm². These technological differences between the subject and predicate device do not impact safety and effectiveness.

Maximum Power Density (mW/cm²) at 500 Ω *calculated along Guidance "Guidance Document for Powered Muscle Stimulator 510(k)s", issued on June 1999, p13-14.* *Maximum power density (mW/cm²) = U (V) x Maximum current density (mA/cm²)* *with* *U and Maximum current density measured above*	P1: 4,23 P2: 2,53 P3: 0,11 P4: 4,23 P5: 3,16 P6: 0,08 or 3,160 P7: 3,16 P8: 0,08 to 1,67 P9 min (30 Hz - 150 µs): 0,94 P9 - EMS 1: 2,65 P9 max (80 Hz - 400 µs): 6,78 P10: 2,53 P11: 2,53 P12: 0,99 P13: 0,38 P15 min (1 Hz - 50 µs): 0,01 P15 max (120 Hz - 400 µs): 10,20	Mode 1: This mode cycles the following modes Mode 2: 0,46 Mode 3:0,16~0,68 Mode 4: 0,02 Mode 5: 0,51 Mode 6: 0,51 Mode 7:0,18 Mode 8: 0,50	Maximum power density of the subject device stays in the same order of magnitude as this of the predicate device (from 0,01 mW/cm² vs 0,02 mW/cm² up to 10,20 mW/cm² vs 0,68 mW/cm²). These values stay well under 0,25 W/cm² as required by the guidance "Guidance Document for Powered Muscle Stimulator 510(k)s", issued on June 1999, p 14, to reduce the risk of thermal burns. These technological differences between the subject and predicate device do not impact safety and effectiveness.
Burst Mode (i.e., pulse trains) a. Pulses per burst b. Bursts per second c. Burst duration (seconds) d. Duty Cycle [Line (b) x Line (c)]	All programs except P7: NA (continuous) Burst mode for TENS functionality: P7 a: 25 b: 2 c: 0.25 d: 0.5	NA	The additional burst mode for TENS functionality does not affect the safety and effectiveness of the device.

ON Time (seconds)	P1: NA (continuous) P2: NA (continuous) P3: NA (continuous) P4: NA (continuous) P5: NA (continuous) P6: NA (continuous) P7: NA (burst) P8: NA (continuous) P9 min (30 Hz - 150 µs):1 P9 - EMS 1:5 P9 max (80 Hz - 400 µs): 60 P10: NA (continuous) P11: NA (continuous) P12: NA (continuous) P13: NA (continuous) P15 min (1 Hz - 50 µs): NA (continuous) P15 max (120 Hz - 400 µs): NA (continuous)	3.4 ~ 20	ON Times stays in the same order of magnitude as those of the predicate (1 to 60 s vs 3.4 to 20 s). These technological differences between the subject and predicate device do not impact safety and effectiveness.

OFF Time (seconds)	P1: NA (continuous) P2: NA (continuous) P3: NA (continuous) P4: NA (continuous) P5: NA (continuous) P6: NA (continuous) P7: NA (burst) P8: NA (continuous) P9 min (30 Hz - 150 µs): 60 P9 - EMS 1: 12 P9 max (80 Hz - 400 µs): 1 P10: NA (continuous) P11: NA (continuous) P12: NA (continuous) P13: NA (continuous) P15 min (1 Hz - 50 µs): NA (continuous) P15 max (120 Hz - 400 µs): NA (continuous)	1 ~ 2.5	OFF Times stays in the same order of magnitude as those of the predicate (1 to 60 s vs 1 to 2.5 s) These technological differences between the subject and predicate device do not impact safety and effectiveness.
Additional features	NA	NA	NA
Number of output channels - *Synchronous or Alternating?* - Method of Channel Isolation:	2 - Alternating - Mechanical	1 - Not publicly disclosed - Not publicly disclosed	The addition of a second channel does not impact the safety or effectiveness of the device because each channel operates independently and within the same electrical output specifications as the predicate.

Regulated Current or Regulated Voltage?	Regulated current	Regulated voltage	. Both approaches deliver therapeutic stimulation within safe and effective ranges. This difference in regulation method does not alter the waveform, treatment parameters, or clinical effect, and therefore does not impact safety or effectiveness.

Software/Firmware/Microprocessor Control?	Yes, software control	Not publicly disclosed	Values of the predicate are not publicly available.
Automatic Overload Trip?	No, overload not possible by design	Not publicly disclosed	Values of the predicate are not publicly available.
Automatic No-Load Trip?	Yes, verification step during program launch and stimulation stops in case of detection of no-load.	Not publicly disclosed	Values of the predicate are not publicly available.
Automatic Shut Off?	Yes, the generator turns off after 10 minutes of no activity.	Not publicly disclosed	Values of the predicate are not publicly available.
Patient Override Control?	Yes, through the mobile app	Not publicly disclosed	Values of the predicate are not publicly available.
Timer Range (minutes)	Session duration:10 -720, adjustable via the mobile app	Not publicly disclosed	Values of the predicate are not publicly available.
Compliance with Voluntary Standards?	Yes (specified at the end of this document*)	Yes	NA: both devices are compliant with voluntary standards
Compliance with 21 CFR 898?	Yes	Yes	NA: No difference
Weight	~ 60 g	Not publicly disclosed	Values of the predicate are not publicly available.
Dimensions (mm) [W x H x D]	92 mm x 15 mm x 56mm	Not publicly disclosed	Values of the predicate are not publicly available.
Indicator Display: - ON/OFF status? - Low battery? - Current level?	Yes:LED indicator / mobile app Yes:Indicated on the mobile app Yes:Indicated on the mobile app	Not publicly disclosed	Values of the predicate are not publicly available.

Performance Testing	The following benchtop performance testing was performed: **Transportation Testing:** - Transportation test report **Self-adhesive strips wearability:** - Wearability test report of the self-adhesive strips **Interoperability:** - Validation report of the system **Usability Testing:** - Validation plan - Usability Engineering File Usability Engineering File – final validation report	Not publicly disclosed	Performance testing carried out on the predicate device is not disclosed.

* Compliance with voluntary standards:

- ISO 14971: 2019
- ISO 15223-1: 2021
- IEC 60601-1:2005+A1:2012+A2:2020
- IEC 62304: 2006 / A1: 2015
- IEC 62366-1: 2015 + A1:2020
- UN38.3
- ISO 20417: 2021
- ISO 17664-2: 2021
- IEC 60601-1-2: 2014 + A1:2020
- IEC 60601-1-6:2010+A1:2013 + A2:2020
- IEC 60601-1-11:2015 + A1:2020
- IEC 60601-2-10: 2012 + A1:2016 + A2:2023
- ISO 10993-1: 2018
- ISO 10993-5: 2009
- ISO 10993-10: 2010
- ISO 10993-12: 2012
- ANSI/HIBCC 2.6: 2016
- ASTM F2503-23e1
- AAMI ANSI NS4
- UL 1642 6th Edition Lithium Batteries
- ASTM D4169-23
- UL 94 ed.7-2023
- UL969 ed. 5-2017
- UL 796 Ed. 12-2020
- CAN/CSA-C22.2 No. 0.17"
- ANSI/UL248-1 Ed.4
- ANSI/UL 497B Ed.4
- UL 2900-2-1
- IEC/TR 60601-4-2
- ASTM F1980-16
- AIM Standard 7351731 Rev. 3.00
- AAMI TIR69:2017/(R2020)
- IEEE ANSI USEMCSC C63.27-2021

VIII. BRIEF DISCUSSION OF NONCLINICAL TESTS

The following nonclinical testing was provided in support of the substantial equivalence determination.

Biocompatibility Testing
• Cytotoxicity Testing (MEM Elution) - ISO 10933-5
• Sensitization Testing (Guinea Pig Maximization) - ISO 10933-10
• Irritation Testing (Intracutaneous Irritation) - ISO 10933-23

Sterilization Validation
Not applicable, because subject device and components are non-sterile and components are not intended to be sterilized by the user.

Shelf-life
Wearability test report of the self-adhesive strips

Software Validation, Cybersecurity, Wireless Safety, and Interoperability
• IEC 62304-1
• Cybersecurity testing
• IEEE/ANSI C63.27-2021 Wireless Coexistence

Electrical Safety & EMC Testing
• IEC 60601-2-10
• IEC 60601-1-11
• IEC 60601-1-6
• IEC 60601-1-2
• IEC 60601-1

Performance Testing (non-clinical benchtop):
• Transportation Testing
• Output waveforms
• Usability Documentation

Performance Testing (animal studies):
Not Applicable, because the device does not require animal studies to demonstrate performance.

IX. BRIEF DISCUSSION OF CLINICAL TESTS

Not Applicable, because the device does not require clinical studies to demonstrate performance.

X. CONCLUSIONS FROM NONCLINICAL AND CLINICAL TESTS

The subject device, actiTENS mini, has the same indications for use when compared with the predicate devices (K202159 and K182203). The subject device and the predicate devices have similar technological characteristics. Non-clinical benchtop testing shows that the subject device is substantially equivalent in terms of safety and effectiveness when compared with the predicate device and performs as well as the predicate.